UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

Department of Anesthesia

Philip S. Kim, M.D.
Pain Medicine Center

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September 29, 2000

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

I am writing in strong opposition to FDA's intention to reclassify Totally Implantable Spinal Cord Stimulators (SCS) from Class III to Class II. Such a move would eliminate some critical checks and balances that help promote patient safety.

SCS devices are extremely complex. They involve highly intricate and specialized circuitry and a power source that is totally implantable with leads surgically placed into the spinal area. The devices themselves are as complex as the procedure to implant them.

I am deeply concerned that the potential reclassification of this device to Class II opens the door to allow a lower standard of product in the market that could potentially endanger the lives of patients. As a physician who treats chronic pain patients on a regular basis, I am greatly concerned for their safety as well as the integrity of my practice.

Even with implantable SCS devices already approved by the FDA, not all safety features are well understood. To ensure patient safety, it is critical to have manufacturing checks for any potential manufacturer of these devices.

I am compelled to note that in 1985, the FDA itself deemed these devices "potentially high risk." The fact that the agency is planning to downgrade them now is cause for great concern.

I firmly believe that reclassification of these devices compromises the integrity of the entire class, a misstep that undoubtedly will jeopardize future patients (many of whom have lived with serious pain for years) from potentially receiving only therapy that could help them. The FDA reclassification level III, with the corresponding Pre-Market Approval, is imperative to protecting the safety of patients receiving these complex technologically-advanced devices.

Please consider this in your decision process as more and more concerns on patient safety regarding to patient medications, technology, and clinically effective therapies become a major issue with our patients. Changing classification of the FDA intention from Class III to Class II could potentially lead to more complications for these chronic pain patients. This is not the time

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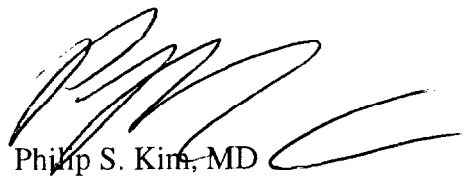
to change this classification. Patient safety should always be paramount in any consideration for making changes.

Thank you for your careful consideration of my comments. Please call me at 215-662-8650 if I can provide you with any additional information.

Sincerely,



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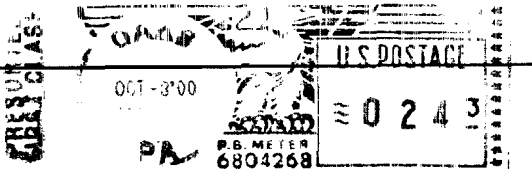

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